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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,021	02/18/2005	Mitsutaka Nakamura	0020-5041PUS2	3141

2292 7590 03/05/2010

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/525,021	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,8,11,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,8,11,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Receipt of Applicants arguments/Remarks amended claims filed on 12/10/09 is acknowledged.

Claims 3-4, 6-7, 9-10, 12-19 and 20-21 have been canceled. New claims 22-23 have been added.

Claims 1, 2, 5 and 8 have been amended.

Accordingly, claims **1-2, 5, 8, 11 and 22-23** are being examined on the merits herein.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 5, 8, 11 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 464846 by Saji et al.

Saji teaches a **method of treatment of schizophrenia** (see page 3, lines 1-4 and page 15). Saji et al. teaches oral preparations of the claimed compound, see page 33. The reference teaches dosage for adult daily dose to be from about 1 mg to 1000 mg, preferably from about 5 to 100 mg and in case of oral dosage to be from about 0.1 mg to 100 mg, preferably from about 0.3 mg to 50 mg, (see page 13, lines 25-30). The reference teaches in Table 4, the amount of compound 101, an antipsychotic, which is same as the instant claimed compound to be 10.3 mg/kg and similar antipsychotic compound to be 26.5 mg/kg on page 15. Since the reference teaches the claimed compound in the claimed dosage for the treatment of the claimed disease that is schizophrenia, it is the position of the examiner that all aspects of the disease such as positive and negative symptoms will be inherent to treatment disclosed in the prior art. Applicants have not defined negative symptoms in the instant application, the disclosure only defines adverse effects which can be either positive or negative adverse effects.

Response to Arguments

4. Applicant's arguments filed 12/10/09 have been fully considered but they are not persuasive.

Applicant argues that Saji EP '846 does not anticipate the present invention. The present claim 1 recites treatment of two particular classes of symptoms of the particular

disease (schizophrenia) by administration of a particular compound (Lurasidone or its salts). On the other hand, as explained in previous responses, Saji EP '846 describes the compound very broadly (see, formula I at p. 4) and names specifically at least 200 compounds that are to be used for "antipsychotic" treatments broadl2£ stated (p. 3, lines 3-4). Nowhere in Saji EP '846 is the particular compound recited in the present claim 1 (Lurasidone) associated with effective treatment of schizophrenia particularly, and especially there is no association of Lurasidone with the treatment of negative symptoms of schizophrenia or with the treatment of cognitive dysfunction arising from schizophrenia. Furthermore, there is no indication in Saji EP '846 that Lurasidone is effective in treating these symptoms without inducing any extrapyramidal symptoms. There is not any recognition by Saji EP '846 that "negative symptoms" are something that should be addressed in an effective treatment of schizophrenia nor that extrapyramidal symptoms are to be avoided.

Appellant further argues that it is well-established that a broad, generic teaching is not anticipatory of a claim directed to a particular combination of elements in the absence of direction within the reference toward that combination. See, *In re Petering* 133 USPQ 275 (CCPA 1962). Saji EP '846 does not provide any such direction as explained above, and so does not anticipate the present invention. Anticipation also requires that each and every feature of the claim be described in the reference. As explained above, Saji EP '846 fails to disclose at least one feature in the present claim 1, and so fails to anticipate claim 1 or the claims dependent therefrom.

These arguments are not well taken. In response to arguments that Saji does not provide association of Lurasidone with the treatment of negative symptoms of schizophrenia or with the treatment of cognitive dysfunction arising from schizophrenia or there is no indication in Saji EP '846 that Lurasidone is effective in treating these symptoms without inducing any extrapyramidal symptoms, the Examiner respectfully points out that the reference teaches the claimed compound in the claimed dosage for the treatment of the claimed disease that is schizophrenia, therefore, it is the position of the examiner that all aspects of the disease such as positive and negative symptoms will be inherent to treatment disclosed in the prior art. Applicants have not defined negative symptoms in the instant application, the instant disclosure only defines adverse effects which can be either positive or negative adverse effects.

In response to applicants arguments that the broad and generic disclosure of Saji et al. does not anticipate the claimed invention, the examiner points out that the prior art specifically teaches treatment of the claimed disease schizophrenia with the claimed amount, thus it is implicit that by administering the claimed compound which is disclosed in prior art would treat adverse side effects including positive and negative symptoms and cognitive dysfunctions associated with schizophrenia.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-2, 5, 8, 11 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 464846 by Saji et al.

Saji teaches a **method of treatment of schizophrenia** (see page 3, lines 1-4 and page 15). Saji et al. teaches oral preparations of the claimed compound, see page 33. The reference teaches dosage for adult daily dose to be from about 1 mg to 1000 mg, preferably from about 5 to 100 mg and in case of oral dosage to be from about 0.1 mg to 100 mg, preferably from about 0.3 mg to 50 mg, (see page 13, lines 25-30). The reference teaches in Table 4, the amount of compound 101, an antipsychotic, which is same as the instant claimed compound to be 10.3 mg/kg and similar antipsychotic compound to be 26.5 mg/kg on page 15.

Although the reference does not teach exactly the same range 5 mg to 120 mg, however, the reference also teaches that the dosage of the imide compound or its pharmaceutically acceptable salt varies greatly with the symptom, age and weight of the patient, the dosage form and the administration mode, see page 13, lines 25-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the amount of drug and arrive at the optimum dosage level by doing experimental manipulations with minimum side effects. It is to be noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955) absent evidence to the contrary. Additionally since the prior art specifically teaches treatment of the claimed

disease schizophrenia with the claimed amount, thus it is obvious that by administering the claimed compound which is disclosed in prior art would treat adverse side effects including positive and negative symptoms and cognitive dysfunctions associated with schizophrenia.

7. Claims 1-2, 5, 8, 11 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommerville et al. (WO 03/066039 A1, presented in IDS) in view of Wong et al. (US 6,964,962) by itself or in view of EP 464846 by Saji et al.

It is noted that (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl-methyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1] heptanedicarboximide hydrochloride is known in the art as SM-13496 (see page 7, lines 5-8 of the specification). Thus, SM-13496 is the hydrochloride salt of (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl-methyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide.

Sommerville et al. teach a method of treating schizophrenia comprising atypical antipsychotics, namely SM-13496 (abstract; and page 5, line 35). Sommerville et al. further teaches positive and negative symptoms are often increased during the acute phase, or the florid psychotic phase, of schizophrinia and that the method of Sommerville et al. is aimed at treatment during the acute phase of schizophrenia (page 4, lines 16-23).

Sommerville et al. do not explicitly teach the dose of SM-13496 (see page 7, lines 23-25).

Wong et al. teach 0.05 to 7500 mg/day/patient of SM-13496 can be used to treat schizophrenia (see column 4, lines 51-58; and Table in column 8, line 16), which details the daily dose of SM-13496 that can be given to the patient and thus may be a once a day administration. Moreover, Wong et al. teach 0.05 to 7500 mg/day/patient of SM-13496 can be used to schizophrenia (column 4, lines 51-58; and Table in column 8, line 16). It would have been obvious too one of ordinary skill in the art to utilize the claimed amounts of 40 and 120 mg of he claimed compound for treating schizophrenia since Wong teaches the same compound for the same disease in a broad range.

While Wong et al. teach wide range of dosage, Saji et al. disclose specific ranges of dosage to treat schizophrenia.

Saji et al. teaches oral preparations of the claimed compound, see page 33. The reference teaches in Table 4, the amount of compound 101 an antipsychotic, which is same as the instant claimed compound to be 10.3 mg/kg and similar antipsychotic compound to be 26.5 mg/kg on page 15. The reference teaches dosage for adult daily dose to be from about 1 mg to 1000 mg, preferably from about 5 to 100 mg and in case of oral dosage to be from about 0.1 mg to 100 mg, preferably from about 0.3 mg to 50 mg, (see page 13, lines 25-30).

The reference also teaches that the dosage of the imide compound or its pharmaceutically acceptable salt varies greatly with the symptom, age and weight of the patient, the dosage form and the administration mode, see page 13, lines 25-30.

It would have been obvious to one of ordinary skill in the art to optimize the dosage range of the claimed drug in order to obtain the most efficacious dosage range by doing experimental manipulations. Based on the teachings of Wong et al. and Saji et al. one would have been motivated to perform experimental manipulations with the dosage range in order to treat schizophrenia in a most efficacious dosage amount as taught by Sommerville et al. It is to be noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955) absent evidence to the contrary. Additionally since the prior art specifically teaches treatment of the claimed disease schizophrenia with the claimed amount, thus it is obvious that by administering the claimed compound which is disclosed in prior art would treat adverse side effects including positive and negative symptoms and cognitive dysfunctions associated with schizophrenia.

8. Claims 1-2, 5, 8, 11 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 6,964,962) by itself or in view of EP 464846 by Saji et al.

Wong et al. teach 0.05 to 7500 mg/day/patient of SM-13496 can be used to treat schizophrenia (see column 4, lines 51-58; and Table in column 8, line 16), which details the daily dose of SM-13496 that can be given to the patient and thus may be a once a day administration. Moreover, Wong et al. teach 0.05 to 7500 mg/day/patient of SM-13496 can be used to schizophrenia (column 4, lines 51-58; and Table in column 8, line

16). It would have been obvious too one of ordinary skill in the art to utilize the claimed amounts of 40 and 120 mg of he claimed compound for treating schizophrenia since Wong teaches the same compound for the same disease in a broad range.

It would have been obvious too one of ordinary skill in the art to utilize the claimed amounts of 40 and 120 mg of he claimed compound for treating schizophrenia since Wong teaches the same compound for the same disease in a broad range.

While Wong et al. teach wide range of dosage, Saji et al. disclose specific ranges of dosage to treat schizophrenia. Since Wong teaches the treatment of schizophrenia in combination and discloses a wide rage of dosage amount and teaches that the selection of the dosage of the first component is that which provides relief to the patient, the dosage of this component depends on several factors such as potency of the selected specific compound, the mode of administration, the age and weight of the patient, the severity of the condition to be treated and this is considered to be within the skill of the artisan and one can review the existing literature on the components to determine optimal dosing (see column 6, lines 49-57) and Saji teaches the claimed drug alone in smaller dosage amounts in treating schizophrenia, one would have been motivated to optimize the amount to achieve best possible dosage amount with minimum side effects.

It would have been obvious to one of ordinary skill in the art to optimize the dosage range of the claimed drug in order to obtain the most efficacious dosage range by doing experimental manipulations. Based on the teachings of Wong et al. and Saji et al. one would have been motivated to perform experimental manipulations with the

dosage range in order to treat schizophrenia in a most efficacious dosage amount. It is to be noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955) absent evidence to the contrary. Additionally since the prior art specifically teaches treatment of the claimed disease schizophrenia with the claimed amount, thus it is obvious that by administering the claimed compound which is disclosed in prior art would treat adverse side effects including positive and negative symptoms and cognitive dysfunctions associated with schizophrenia.

(Applicants have collectively argued the obviousness rejections)

Response to Arguments (obviousness)

9. Applicant's arguments filed 12/10/09 have been fully considered but they are not persuasive.

Applicants argue that it is true that it has been known that negative symptoms are included in the symptoms of schizophrenia. However, it has been considered before filing of the present application that the known drugs for treatment of schizophrenia are effective for the treatment of positive symptoms of schizophrenia but not sufficiently effective for the treatment of negative symptoms of schizophrenia. At the time the present application was filed, there was no drug sufficiently effective for the treatment of

negative symptoms of schizophrenia. This long-felt need in the art is reflected in many publications. Applicant cites the following papers in this regard:

Reference 1 : Stephen M. Erhart et al., "Treatment of Schizophrenia Negative Symptoms:
Future Prospects", Schizophrenia Bulletin, vol. 32, no. 2, pp. 234-237, 2006
Reference 2: Thomas Laughren et al., "Food and Drug Administration Perspective on Negative Symptoms in Schizophrenia as a Target for a Drug Treatment Claim", Schizophrenia Bulletin, vol. 32, no. 2, pp. 220-222, 2006
Reference 3: Larry Alphs, "An Industry Perspective on NIMH Congress Statement on Negative Symptoms", Schizophrenia Bulletin, vol. 32, no. 2, pp. 225-230, 2006
Reference 4: John Kane, "Commentary: Consensus Statement on Negative Symptoms",
Schizophrenia Bulletin, vol. 32, no. 2, pp. 223-224, 2006
Reference 5: Brian Kirkpatrick et al., "The NIMH-MATRICS Consensus Statement on Negative Symptoms", Schizophrenia Bulletin, vol. 32, no. 2, pp. 214-219, 2006

Applicant adds that although published post-filing of the present application, these papers show that, even a few years after the priority date, the art of treatment of schizophrenia did not include any approved treatment that addressed negative symptoms of the disease. As mentioned in the Abstract and/or introductory passages of these papers, finding an agent effective for the treatment of negative symptoms of schizophrenia has been the object of a great deal of research effort, but the available drugs for schizophrenia do not exhibit sufficient effect upon the treatment of negative symptoms in schizophrenia. Applicant argues that Laughren et al. suggest that negative symptoms of schizophrenia might represent a completely different target for drug development from the positive symptoms of the disease. Alphs states in his abstract that, "Negative symptoms of schizophrenia remain an area of substantial unmet clinical need." Applicant points that the failure of others to solve a problem and the solving of a long-felt need are two of several secondary considerations deemed by the

Supreme Court to be strong evidence of unobviousness of an invention. Following intensive study, the present inventors found that lurasidone shows the desired effects on negative symptoms in schizophrenia. The effects of the compound are provided as Reference 6: A poster exhibited at the 18th European College of Neuropsychopharmaco!ogy Congress, Amsterdam, Netherlands, October 22-26, 2005. Fig. 2 of the poster shows the PANSS (= positive and negative syndrome scale) scores for the compound of the present invention. Lurasidone showed significantly higher effectiveness on the negative symptoms of schizophrenia in comparison with placebo in a clinical study. Based on the paper,

Applicants argue that Lurasidone was shown to be the first effective treatment for negative symptoms of schizophrenia and furthermore was also effective in treating the cognitive dysfunction of schizophrenia as well. Given the failure of previous treatments available in the art to address these two classes of symptoms and to do so without also causing undesirable extra pyramidal symptoms (sedation) these results must be considered unexpected by those of ordinary skill in the art *(e.g.,* as established by the five references attached hereto). Furthermore, these results represent a solution to a problem that many others have failed to solve, and furthermore solve a long-felt need in the art of treatment of schizophrenia and thus provide substantial, objective evidence of unobviousness of the present invention.

Applicants further argue that the present inventors have also newly found that Lurasidone is also effective to treat cognitive dysfunction of schizophrenia, as is also proved by the clinical study reported in the poster Reference 6. The Examiner should again note Fig. 2 showing the PANSS in cognitive function: Lurasidone showed significantly higher effectiveness upon cognitive dysfunction of schizophrenia in

comparison with a placebo in the clinical study. Applicant therefore argues that no such invention has been done earlier as such the rejections shall be withdrawn.

Applicant's arguments are not persuasive because the reference teaches the claimed compound in the claimed dosage for the treatment of the claimed disease that is schizophrenia, therefore, it is the position of the examiner that treatment of all aspects of the disease such as positive and negative symptoms will be obvious to treatment disclosed in the prior art. Applicants have not defined negative symptoms in the instant application, the instant disclosure only defines adverse effects which can be either positive or negative adverse effects, since Saji does disclose the claimed compound in claimed range, thus one of ordinary skill would envision based on the given dosage range of 1mg to 1000 mg of the claimed compound of prior art that any given amount that falls within the disclosed amount would work based on the teachings of the prior art. In response to applicant's arguments that Saji does not disclose treating negative symptoms of Schizophrenia, it is pointed out that Saji teaches the claimed amounts of the claimed compound in treating the claimed disease, therefore, it would have been within the purview of a skilled artisan to come to the optimum amount to treat all aspects of schizophrenia. Additionally, the instant claims do not recite the amount per kg or per mg needed for the treatment, as such the amount of the compound which would be effective in treating adverse (positive or negative) effects of schizophrenia will be obvious to one of ordinary skilled in the art by doing experimental manipulations. There is nothing in the Saji's reference which describes that negative symptoms were still

prevailing while treating schizophrenia with the claimed compound. Similarly Sommerville and Wong teach the claimed compound for the treatment of the claimed disease. Since prior art disclosed in the obviousness rejections disclose the same amount as claimed instantly, one of ordinary would have expected the treatment of schizophrenia with no negative side effects.

In response to applicant's arguments regarding secondary considerations, it is pointed out that the prior art references do not deal with the claimed compound Lurasidone and pertain to different drugs other than lurasidone and those drugs may not be effective in treating negative symptoms of Schizophrenia, however, in the instant case as discussed above, prior art teaches the treatment of schizophrenia with the claimed compound in an overlapping dosage amount, thus the invention would be considered obvious and not unexpected. In response to applicant's arguments that figure 1 teaches treatment positive and negative symptoms and extrapyramidal symptoms, the examiner points out that instant specification in figure 1 teaches adverse events and side effects. It is not clear which are negative symptoms and which are positive symptoms. In response to applicant's arguments regarding treatment of cognitive dysfunction, it is the position of the examiner that even though the reference does not provide such explicit teachings, it is implicit that prior art's compound and dosage which is same as the claimed drug and dosage used for the treatment of schizophrenia would treat the side effects such as cognitive dysfunctions associated with schizophrenia. The rejection will be maintained.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612